UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF

SEP 3 0 2005

(AE-17J)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cindalee Walsh
Director, Environmental Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Walsh:

Enclosed is a file stamped Consent Agreement and Final Order (CAFO) which resolves the violations we've been discussing. As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on SEP 3 0 2005.

Pursuant to paragraph 48 of the CAFO, Pharmacia & Upjohn Company must pay the civil penalty within 30 days of SEP 3 0 2005. Your check must display the case docket number, CAA-05- 2006 0063, and the billing document number, 050305066

Please direct any questions regarding this case to Reginald Pallesen, Associate Regional Counsel at 312.886.6055.

Sincerely yours,

William MacDowell
Section Chief, AECAS (MN/OH)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

IN THE MATTER OF:	)	**Docket No.** CAA-05- 2006 0063
	)	
Pharmacia & Upjohn Company LLC,	)	**Proceeding to Assess a Civil**
	)	**Penalty under Section 113(d) of the**
Respondent.	)	**Clean Air Act, 42 U.S.C. § 7413(d)**
	)	

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (the Act), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b), and 22.18(b) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules) as codified at 40 C.F.R. Part 22 (2004).

2. Complainant is the Director of the Air and Radiation Division, United States Environmental Protection Agency, Region 5 (U.S. EPA).

3. Respondent is Pharmacia & Upjohn Company LLC (Pharmacia), a corporation doing business in the State of Michigan.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a Consent Agreement and Final Order (CAFO). 40 C.F.R. § 22.13(b) (2004).

5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Pharmacia consents to entry of this CAFO and the assessment of the specified civil penalty, and agrees to comply with the terms of the CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Pharmacia admits the jurisdictional allegations in this CAFO, and neither admits nor denies the factual allegations and the alleged violations set out in this CAFO.

8. Pharmacia waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO in this proceeding, and its right to appeal this CAFO.

Statutory and Regulatory Background

9. Under Section 112 of the Act, the Administrator of U.S. EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Equipment Leaks at 40 C.F.R. Part 63, Subparts F and H, the NESHAP for Pharmaceutical Production at 40 C.F.R. Part 63, Subpart GGG, and EPA Reference Method 21 at 40 C.F.R. Part 60 Appendix A.

10. The NESHAP provisions for Equipment Leaks and the NESHAP provisions for Pharmaceutical Production apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessel, bottoms receivers, instrumentation systems, and control devices or closed vent systems that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year.

11. The NESHAP for Equipment Leaks was proposed on December 31, 1992 and became final on April 22, 1994. The owner or operator of an existing affected source must comply with the provisions of this NESHAP no later than October 24, 1994, for the Group I category. 40 C.F.R. § 63.100(k)(3)

12. The NESHAP for Pharmaceutical Production was proposed on September 21, 1998 and became final on September 21, 2001. The owner or operator of an existing affected source must comply with the provisions of this NESHAP no later than October 21, 2002. 40 C.F.R. § 63.1250(f)

13. The NESHAP, at 40 C.F.R. § 63.4(a)(1), provides that no owner or operator subject to the provisions of this part shall operate any affected source in violation of this requirement of this part except under an applicable extension of compliance.

14. The NESHAP, at 40 C.F.R. § 63.168(b), requires the owner or operator of a source subject to this subpart to monitor all valves at intervals specified in this section.

15. The NESHAP, at 40 C.F.R. § 63.1255 (e)(3), requires the owner or operator of a source subject to this subpart to monitor all valves at intervals specified in this section.

16. The NESHAP, at 40 C.F.R. § 63 1255(e)(4)(iv), provides that for a group of processes with less than 0.5 percent leaking valves, the owner or operator may elect to monitor each valve once every 4 quarters.

17. The NESHAP, at 40 C.F.R. § 63.174(a)(1), requires the owner or operator of a source subject to this subpart to monitor all connectors, at intervals specified in this section.

18. The NESHAP, at 40 C.F.R. § 63.180(f), specifies procedures to be used to pressure test batch product process equipment for pressure or vacuum loss to demonstrate compliance with the requirements of this subpart.

19. The NESHAP, at 40 C.F.R. § 63.1255(b), requires the owner or operator of a source subject to the provisions of this subpart to comply with the test methods and procedures requirements provided in this section.

20. The NESHAP, at 40 C.F.R. § 63.180(b)(1), requires the owner or operator of a source to comply with the monitoring procedures and requirements of Method 21 of 40 C.F.R. Part 60 Appendix A.

21. The NESHAP, at 40 C.F.R. § 63.1258(h)(3), requires the owner or operator of a source to comply with the monitoring procedures and requirements of Method 21 of 40 C.F.R. Part 60 Appendix A.

22. Method 21 of 40 C.F.R. Part 60 Appendix A requires the owner or operator to slowly sample the interface where leakage is indicated until the maximum meter reading is obtained.

23. The NESHAP, at 40 C.F.R. § 63.167(a)(1), provides that each open ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve.

24. The NESHAP, at 40 C.F.R. § 63.1255(d)(i), provides that each open ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve.

25. The NESHAP, at 40 C.F.R. § 63.167(a)(2), provides that the cap, blind flange, plug, or second valve shall seal the open end at all times except during operation requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.

26. The NESHAP, at 40 C.F.R. § 63.1255(d)(1)(ii), provides that the cap, blind flange, plug, or second valve shall seal the open end at all times except during operation requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.

27. The NESHAP, at 40 C.F.R. § 63.167 (c), provides that when a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with (d)(1) of this section at all times.

28. The NESHAP, at 40 C.F.R. § 63.1255 (d)(3), provides that when a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with (d)(1) of this section at all times

29. The NESHAP, at 40 C.F.R. § 63.167 (b), provides that each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed.

30. The NESHAP, at 40 C.F.R. § 63.1255 (d)(2), provides that each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed.

31. The NESHAP, at 40 C.F.R. § 63.1255(c)(3)(i), requires that a leak detected as defined by this section be repaired as soon as practicable but no later than 15 calendar days after it is detected, except when the repair is not technically feasible without a process shutdown, or repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown.

32. The Administrator of U.S. EPA (the Administrator) may assess a civil penalty of up to $27,500 per day of violation up to a total of $220,000 for NESHAP violations that occurred from January 31, 1997 through March 15, 2004, and may assess a civil penalty of up to $32,500 per day of violation up to a total of $270,000 for violations that occurred after March 15, 2004 under Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19 (2004).

33. Section 113(d)(1) of the Act limits the Administrator's authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

34. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this CAFO.

Factual Allegations

35. Pharmacia manufactures prescription medicines for humans and animals.

36. Pharmacia owns and operates a pharmaceutical manufacturing plant located at 7000 Portage Road in Kalamazoo, Michigan 49001.

37. Pharmacia is an existing source required to demonstrate compliance with applicable sections of 40 C.F.R. Part 63, Subparts GGG, H and F.

38. During inspections on March 10, 2004 and August 10-12, 2004, U.S. EPA conducted record review and "leak detection and repair" (LDAR) monitoring on process equipment and components at the Pharmacia facility subject to 40 C.F.R. Part 63, Subparts GGG, H and F, per EPA Reference Method 21, and alleges that it discovered evidence of the following violations.

Alleged Violations

39. Pharmacia failed to monitor certain valves on a formaldehyde line at the facility at specified intervals, in violation of 40 C.F.R. § 63.168(b) and 40 C.F.R. §§ 63.1255(e)(3) and 63.1255(e)(4)(iv).

40. Pharmacia failed to monitor certain connectors on a formaldehyde line at the facility at specified intervals, in violation of 40 C.F.R. § 63.174(a)(1).

41. Pharmacia failed to comply with certain monitoring procedures and requirements of Method 21, in violation of 40 C.F.R. § 63.180(b)(1) and 40 C.F.R. § 63.1258(h)(3).

42. Pharmacia failed to follow certain portions of Method 21 of 40 C.F.R. Part 60 Appendix A when monitoring for the LDAR Program.

43. Pharmacia failed to equip certain open valves and lines with a cap, blind flange, plug, or a second valve, in violation of 40 C.F.R. § 63.167(a)(1) and 40 C.F.R. § 63.1255(d)(i).

44. Pharmacia failed to seal certain open-end valves and lines at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair, in violation of 40 C.F.R. § 63.167(a)(2) and 40 C.F.R. § 63.1255(d)(1)(ii).

45. Pharmacia allowed bleed valves or lines to remain open, when a double block was in place, during operations other than venting the lines between the block valves, in violation of 40 C.F.R. § 63.167(c) and 40 C.F.R. § 63.1255(d)(3).

46. Pharmacia failed to operate in a manner such that the valve on the process fluid end is closed before the second valve is closed, in violation of 40 C.F.R. § 63.167(b) and 40 C.F.R. § 63.125(d)(2).

Civil Penalty

47. Based on analysis of the factors specified in Section 113(e) of the Act, 42 U.S.C. § 7413(e), the facts of this case, and Pharmacia's cooperation in this matter, prompt return to compliance, and agreement to perform the Supplemental Environmental Projects (SEPs) set out below, U.S. EPA has determined that an appropriate civil penalty to settle this action is $46,250.

48. Pharmacia must pay the $46,250 civil penalty by cashier's or certified check payable to the "Treasurer, United States of America," within 30 days after the effective date of this CAFO.

49. Pharmacia must send the check to:

U.S. Environmental Protection Agency
Region 5
P.O. Box 70753
Chicago, Illinois 60673

50. A transmittal letter, stating Pharmacia's name, complete address, the case docket number, and the billing document number must accompany the payment. Pharmacia must write the case docket number and the billing document number on the face of the check. Pharmacia must send copies of the check and transmittal letter to:

Attn: Regional Hearing Clerk, (E-19J)
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

Attn: Compliance Tracker, (AE-17J)
Air Enforcement and Compliance Assurance Branch
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

Reginald A. Pallesen
Office of Regional Counsel (C-14J)
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

51. This civil penalty is not deductible for federal tax purposes.

52. If Pharmacia does not pay timely the civil penalty, or any stipulated penalties due under paragraph 66, below, U.S. EPA may bring an action to collect any unpaid portion of the penalty with interest, nonpayment penalties and the United States' enforcement expenses for the collection action under Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

53. Interest will accrue on any overdue amount from the date payment was due at a rate established under 31 U.S.C. § 3717. Pharmacia will pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue according to Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). This nonpayment penalty will be 10 percent of the aggregate amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter.

Supplemental Environmental Project

54. Pharmacia agrees to complete two supplemental environmental projects (SEPs) designed to further protect the environment and public health by reducing fugitive emissions of Hazardous Air Pollutants from its Kalamazoo facility. The first SEP is an equipment replacement and enhancement project. The second SEP is an enhanced Leak Detection and Repair (LDAR) project.

55. At its Kalamazoo facility, Pharmacia must complete an equipment replacement and enhancement SEP as follows, and as detailed in the attached SEP Scope of Work which is incorporated by reference into this CAFO:

a. replace one agitator and provide new seal technology for two other agitators in HAP service; and

b. replace eight pumps in HAP service with seal-less pumps.

56. Pharmacia must spend at least $625,000 for the equipment replacement and enhancement SEP.

57. Pharmacia must submit a SEP completion report for the equipment replacement project to U.S. EPA within one year of the effective date of this CAFO. This completion report must contain the following information:

a. a detailed description of the SEP as completed;

b. a description of any operating problems and the actions taken to correct the problems;

c. itemized costs of goods and services used to complete the SEP documented by copies of invoices, purchase orders, or cancelled checks that specifically identify and itemize the individual costs of the goods and services; and

d. a certification that Pharmacia has completed the SEP in compliance with this CAFO.

58. Pharmacia agrees to perform an enhanced LDAR SEP as follows, and as detailed in the attached SEP Scope of Work (SOW) which is incorporated by reference into this CAFO:

a. perform LDAR monitoring for connectors, valves and pumps in HAP service, more frequently than required under the LDAR regulations, for a period of one (1) year, beginning on January 1, 2006:

i. monitor ½ of the connectors at the facility annually, all valves semi-annually, and all pumps quarterly;

ii. perform monitoring and report results per the requirements of this CAFO and the SOW, using U.S. EPA Reference Method 21;

iii. utilize an instrument that meets Method 21 specifications and is equipped with a data logger which automatically records the emission levels detected at each component and the date and time that each sample is taken. (If an equivalent or superior data recording instrument becomes available, Pharmacia may request approval to use such instrument.);

b. utilize a reduced leak "repair action level" standard (below the regulatory leak definition) for connectors, valves and pumps as follows: 250 ppm for connectors; 250 ppm for valves; and 500 ppm for pumps. These leak levels will trigger repair as described in the Pharma-MACT and HON regulations at 40 C.F.R. Part 63, Subparts, GGG and H, but are not otherwise applicable for regulatory purposes;

c. conduct a general review of the following: results of the LDAR monitoring to attempt to determine potential "root causes" and sources of such leaks, evaluating factors such as whether certain process lines or areas of the plant have substantially higher leak rates than others; whether volatility, vapor pressure, temperature fluctuations, pressure fluctuations, and/or vibration in such lines or areas promote leaks; and whether components from certain manufacturers are less reliable or have higher leak rates than components from other manufacturers.

59. Pharmacia must spend at least $5,000 for the enhanced LDAR SEP.

60. Pharmacia must submit a SEP completion report for the enhanced LDAR project to U.S. EPA by January 15, 2007. This completion report must contain the following information:

a. a detailed description of the SEP as completed;

b. the results of the LDAR monitoring, including individual monitoring data from the data loggers, (submitted in a spreadsheet on a compact disc utilizing the company's LEAKDAS program);

c. a description of the equipment leaks detected during the year, including both leaks above the regulatory leak definition and leaks above the repair action levels set out in paragraph 58 above; a list of all repairs made, including dates of leak detection, first attempt at repair, and final repair; and a summary of the general root cause review;

d. an estimate of the costs incurred to implement the enhanced monitoring SEP; and

e. a certification that Pharmacia has completed the SEP in compliance with this CAFO.

61. Pharmacia certifies that it is not required to perform or develop either the equipment replacement and enhancement SEP or the enhanced LDAR SEP by any law, regulation, grant, order, or agreement, or as injunctive relief as of the date it signs this CAFO. Pharmacia further certifies that it has not received, and is not negotiating to receive, credit for the SEPs in any other enforcement action.

62. U.S. EPA may inspect the facility at any time to monitor Pharmacia's compliance with this CAFO's SEP requirements.

63. Pharmacia must submit all notices and reports required by this CAFO by first class mail to:

Attn: Compliance Tracker (AE-17J)
Air Enforcement and Compliance Assurance Branch
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

64. In each report that Pharmacia submits as provided by this CAFO, it must certify that the report is true and complete by including the following statement signed by a responsible corporate official or an authorized designee:

> I certify that I am familiar with the information in this document and that, based on my inquiry of those individuals responsible for obtaining the information, the information is true and complete to the best of my knowledge. I know that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

65. Following receipt of each SEP completion report described in paragraphs 57 and 60 above, U.S. EPA will notify Pharmacia in writing within 30 days or receipt of each report that:

a. it has satisfactorily completed the SEP and the SEP report;

b. there are deficiencies in the SEP as completed or in the SEP report and U.S. EPA will give Pharmacia 30 days to correct the deficiencies; or

c. it has neither satisfactorily completed the SEP or the SEP report, and U.S. EPA will seek stipulated penalties under paragraph 66, below.

Alternatively, if subparagraph (b) above has been invoked, U.S. EPA will timely notify Pharmacia in writing, that:

a. it has satisfactorily cured deficiencies in the SEP or the SEP report; or

b. it has failed to cure deficiencies in SEP or the SEP report within the allotted time, and U.S. EPA will seek stipulated penalties under paragraph 66, below.

66. If Pharmacia violates any requirement of this CAFO relating to the SEPs, and has failed to cure any deficiencies as provided in paragraph 65 above, Pharmacia must pay stipulated penalties to the United States as follows:

a. If Pharmacia fails to complete the equipment replacement and enhancement SEP in a timely manner, as required by this CAFO and the SOW, including spending at least 90% of the amount specified in paragraph 56 above to implement the SEP, Pharmacia must pay a stipulated penalty in the amount of $138,750;

b. If Pharmacia fails to complete the enhanced LDAR SEP in a timely manner, as required by this CAFO and the SOW, including spending at least 90% of the amount specified in paragraph 59 above to implement the SEP, Pharmacia must pay a stipulated penalty in the amount of $25,000.

67. U.S. EPA's determinations of whether Pharmacia completed each SEP as required by the CAFO and the SOW will bind Pharmacia. If Pharmacia disputes U.S. EPA's initial determination regarding completion of a SEP, Pharmacia must notify U.S. EPA in writing within 10 days of receipt of U.S. EPA's determination. Thereafter, U.S. EPA's final determination of whether Pharmacia completed the SEP as required by the CAFO and the SOW will be made by the U.S. EPA, Region 5, Air and Radiation Division Director, after considering Pharmacia's position.

68. Pharmacia must pay any stipulated penalties within 15 days of receiving U.S. EPA's written demand for the penalties. Pharmacia will use the method of payment specified in paragraphs 48, 49 and 50, above, and will pay interest and nonpayment penalties on any overdue amounts.

69. If an event occurs which causes or may cause a delay in completing a SEP as required by this CAFO:

a. Pharmacia must notify U.S. EPA in writing within 10 days after learning of an event which caused or may cause a delay in completing the SEP. The notice must describe the anticipated length of the delay, its cause(s), Pharmacia's past and proposed actions to prevent or minimize the delay, and a schedule to carry out those actions. Pharmacia must take all reasonable actions to avoid or minimize any delay. If Pharmacia fails to notify U.S. EPA according to this paragraph, Pharmacia will not receive an extension of time to complete the SEP.

b. If the parties agree that circumstances beyond the control of Pharmacia caused or may cause a delay in completing the SEP, the parties will stipulate to an extension of time no longer than the period of delay.

c. If U.S. EPA does not agree that circumstances beyond the control of Pharmacia caused or may cause a delay in completing the SEP, U.S. EPA will notify Pharmacia in writing of its decision and any delays in completing the SEP will not be excused. If Pharmacia disputes U.S. EPA's initial determination regarding delay, Pharmacia must notify U.S. EPA in writing within 10 days of receipt of U.S. EPA's determination. Thereafter, U.S. EPA's final determination of whether circumstances beyond the control of Pharmacia caused or may cause a delay in completing the SEP will be made by the U.S. EPA, Region 5, Air and Radiation Division Director, after considering Pharmacia's position.

d. Pharmacia has the burden of proving that circumstances beyond its control caused or may cause a delay in completing the SEP. Increased costs for completing the SEP will not be a basis for an extension of time under subparagraph b, above. Delay in achieving an interim step will not necessarily justify or excuse delay in achieving subsequent steps.

70. Any statement to the general public that Pharmacia makes referring to the SEPs must include the following language, "Pharmacia undertook this project under the settlement of the United States Environmental Protection Agency's enforcement action against Pharmacia for alleged violations of Clean Air Act requirements regarding equipment standards and monitoring for equipment leaks."

Final Statement

71. This CAFO resolves only Pharmacia's liability for federal civil penalties for the violations alleged in the Alleged Violations section of this CAFO.

72. This CAFO does not affect the right of U.S. EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

73. Except as provided in paragraph 71 above, this CAFO does not affect Pharmacia's responsibility to comply with the Clean Air Act and other applicable federal, state and local laws, and regulations. Except as provided in paragraph 71 above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws and regulations administered by U.S. EPA.

74. Pharmacia hereby certifies that, as of the date of this CAFO, it is complying fully with the NESHAP for Equipment Leaks and the NESHAP for Pharmaceutical Production, and is properly implementing EPA Reference Method 21. Pharmacia has submitted to U.S. EPA documentation indicating that it has in place procedures to allow proper implementation of the EPA Reference Method 21 monitoring required by the enhanced LDAR SEP herein and applicable LDAR regulations.

75. This CAFO constitutes an "enforcement response" as that term is used in "U.S. EPA's Clean Air Act Stationary Source Civil Penalty Policy" to determine Pharmacia's "full compliance history" under Section 113(e) of the Act, 42 U.S.C. § 7413(e).

76. The terms of this CAFO bind Pharmacia, and its successors, and assigns.

77. Each person signing this consent agreement certifies that he or she has the authority to sign this consent agreement for the party whom he or she represents and to bind that party to its terms.

78. This CAFO will terminate upon: Pharmacia's payment of the civil penalty pursuant to paragraph 48 herein; and U.S. EPA's notification that Pharmacia has successfully completed the SEPs and SEP reports pursuant to paragraph 65 herein and/or paid any required stipulated pursuant to paragraph 66 herein, as applicable.

79. Each party agrees to bear its own costs and attorneys' fees in this action.

80. This CAFO and the attached and incorporated Scope of Work constitutes the entire agreement between the parties.

CONSENT AGREEMENT AND FINAL ORDER
Pharmacia & Upjohn Company LLC
Docket No.

~~CAA-05-~~ 2006 0063

U.S. Environmental Protection Agency, Complainant

Wilder 21, 2005
Date

per
Stephen Rothblatt, Director
Air and Radiation Division
U.S. Environmental Protection
Agency, Region 5 (A-18J)

CONSENT AGREEMENT AND FINAL ORDER
Pharmacia & Upjohn Company LLC
Docket No.

CAA-05- 2005 0063

Pharmacia & Upjohn Company LLC, Respondent

9/29/2005
Date

Niall Condon
Site Leader
Pfizer Global Manufacturing

CONSENT AGREEMENT AND FINAL ORDER
Pharmacia & Upjohn Company LLC
Docket No. CAA-05- 2006 0063

Final Order

It is ordered as agreed to by the parties and as stated in the Consent Agreement, effective immediately upon filing of this CAFO with the Regional Hearing Clerk. This final order disposes of this proceeding pursuant to 40 C.F.R. § 22.18.

9-30-05
Date

Thomas V. Skinner
Regional Administrator
U.S. Environmental Protection
Agency, Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604-3511

CERTIFICATE OF SERVICE

I, Loretta Shaffer, hereby certify that I have caused the original of the foregoing Complaint and Consent Agreement and Final Order (CAFO) to be filed with the Regional Hearing Clerk, Region 5, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, and a copy of the CAFO to be served upon the persons designated below, on the date below, by depositing a copy in the U.S. Mail, certified-return receipt requested, in an envelope addressed to:

Cindalee Walsh
Director, Environmental Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Port-41-1
Kalamazoo, MI 49001

Gary Spies
Pharmacia & Upjohn Company
7000 Portage Road
Port-91-106
Kalamzoo, MI 49001

'05 SEP 30 P2:34

and by first-class mail to:

Dale Turton
Michigan Environmental Protection Agency
7953 Adobe Road
Kalamazoo, MI 49009

on the 30th day of Sept, 2005.

Loretta Shaffer
AECAS ([MN/OH])

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0005 9025 6510

CAA-05- 2005 0063

SCOPE OF WORK

SUPPLEMENTAL ENVIRONMENTAL PROJECT

EQUIPMENT REPLACEMENT AND ENHANCEMENT PROJECT

Project Scope
-Replace 8 single-seal pumps, associated with solvent storage tanks, with seal-less pumps
-Replace 1 agitator (T-205 in Building 38) with new agitator equipped with new seal technology
-Install new seal technology on 2 agitators (on ST-319 and ST-320)

Project Costs
Pharmacia & Upjohn Company LLC (Pharmacia) will spend a minimum of $625,000 for all of the following:

-Engineering/design costs
-Demolition costs
-Equipment purchases (e.g. instrumentation, piping, process/mechanical equipment)
-Required utility piping and tie-ins (e.g. electrical for pump starters)
-Automation/Instrumentation/Controls
-Spare parts and equipment (e.g. spare pumps required)
-All installation costs, including any start-up costs

Reporting
Pharmacia will submit to EPA a SEP completion report regarding the Equipment Replacement and Enhancement Project, as required by the CAFO in this matter.

SCOPE OF WORK

SUPPLEMENTAL ENVIRONMENTAL PROJECT

ENHANCED LEAK DETECTION AND REPAIR PROGRAM

Project Scope

Pharmacia will conduct an Enhanced LDAR Program during the period of January 1, 2006 through December 31, 2006. A final report required by the CAFO in this matter will be submitted to EPA by January 15, 2007.

Monitoring conducted during 2006 to fulfill Pharmacia's regulatory LDAR requirements may also constitute monitoring for the Enhanced LDAR Program, provided that Pharmacia complies with the additional repair and reporting requirements of the Enhanced LDAR Program for such monitoring. Pharmacia may not credit costs incurred for such "dual monitoring" as costs incurred to implement the Enhanced LDAR Program. Costs incurred for monitoring undertaken solely to implement the Enhanced LDAR Program, such as one of the two semi-annual valve monitorings, as well as all accelerated repair costs occasioned by the "repair action levels," costs for any risk analysis or leak review undertaken, and reasonable costs to administer and report on the Enhanced LDAR Program, may be credited as costs to implement the Enhanced LDAR Program.

The Enhanced LDAR Program covers all components in HAP light liquid or gas service greater than 300 hours per year that Pharmacia has monitored by an organic vapor analyzer in accordance with EPA Reference Method 21 under 40 C.F.R. Part 63, Subparts GGG and H. The Enhanced LDAR Program does not include those components that Pharmacia has monitored under a batch pressure testing program. An organic vapor analyzer with a data logger that meets EPA Reference Method 21 requirements is required for monitoring.

Program Requirements

Under the Enhanced LDAR program, monitoring frequencies will increase, with the exception of pumps, and repairs will be conducted in accordance with the regulatory requirements of C.F.R. Part 63, Subpart GGG and H when triggered by the Enhanced LDAR "repair action level" per Table 1 below. Any component for which the regulatory applicability status changes, and causes it to no longer be subject to regulation (e.g. replacement with seal less pumps), will be removed from the Enhanced LDAR Program. Removal or permanent shutdown of equipment that results in affected components no longer being subject to the regulatory requirements of C.F.R. Part 63, Subpart GGG or H will exempt such components from the Enhanced LDAR Program. However, Pharmacia may not substitute large-scale pressure testing to diminish the scope of the Enhanced LDAR Program.

Regulatory Requirements

Results of all LDAR monitoring undertaken in 2006, including both that performed for regulatory purposes and that performed for the Enhanced LDAR Program, setting out leak rates calculated using the applicable regulatory leak definitions, must be submitted in the periodic reports required by the applicable Pharma-MACT and HON regulations at 40 C.F.R. Part 63, Subparts GGG and H, for purposes of determining required monitoring schedules for 2007.

TABLE 1

Component	Current Regulatory Monitoring Frequency	Enhanced LDAR Frequency	Regulatory Leak Definition	Enhanced LDAR "Repair Action Level"
Pumps	Quarterly	Quarterly	2000 ppm	500 ppm
Connectors	Over a 4 year period	1 year (1/2 of total per yr)*	500 ppm	250 ppm
Valves	Annual	Semiannual	500 ppm	250 ppm

Reporting

Pharmacia will submit to EPA a SEP completion report regarding the Enhanced LDAR Program, as required by the CAFO in this matter, by January 15, 2007. The Enhanced LDAR Program completion report will include the following information:

- The results of the LDAR monitoring, including individual monitoring data from the data loggers, (submitted in a spreadsheet on a compact disc utilizing the company's LEAKDAS program). Leak rates per component type (pumps, valves and connectors) calculated based on both the regulatory leak definition and on the repair action levels under the Enhanced LDAR Program.
- A description of the equipment leaks detected during the year, including both leaks above the regulatory leak definition and leaks above the repair action levels
- A list of all repairs made, including dates of leak detection, first attempt at repair, and final repair.
- A summary of the general root cause review;
- An estimate of the costs incurred to implement the Enhanced LDAR Program; and
- A certification that Pharmacia has completed the SEP in compliance with the CAFO.

*Only one year of connector monitoring is part of this SEP Scope of Work where ½ of the total connectors will be monitored.

Case Conclusion Data Sheet - (Revised 2004)

Click Here to View the CCDS Training Booklet in EDMS

Status: ● Draft ○ Final

Program Contact :	**Shilpa Patel**	**Phone:**
ORC Attorney :	**Reginald Pallesen**	**Phone:**

A. CASE and FACILITY BACKGROUND

1. ICIS Enforcement Activity ID:

2. Enforcement Action Name: **Pharmacia & Upjohn**
   Settlement Name:
   Document Number:
3. Settlement Type: **Federal facility compliance agreement (not including RCRA matters)**
4. Was Alternative Dispute Resolution used in this action? ○ Yes ● No
5. Was an Environmental Management Review requested for this action? ○ Yes ● No

   Date Final Order Issued.
7. Respondent Name(s):
8. Federal Statute(s)/Sections Violated: **CAA 112D - MACT Standards**

9. Facility Name: **Pharmacia & Upjohn Company, L.L.C.**
10. Facility Address: **7000 Portage Road**
    Facility City: **Kalamazoo**
    Facility State: **MI**
    Facility Zip Code: **49001**
    Facility County:

- Primary 4-digit NAICS/SICCode: 2834
- Other 4-digit NAICS/SIC codes:

B. PENALTY

11. For multi-media actions **only**, enter the Federal penalty amounts by Statute:

Statute	Amount
CAA	
CERCLA	
CWA 402	
CWA 311	
CWA 404	
EPCRA 304/312/325	
EPCRA 313	
FIFRA	
RCRA	
RCRA/UST	
SDWA/UIC	
TSCA	

Penalty Amount Sought:	
Total Penalty Required:	

12.	Federal Penalty Required:	$46,250.00
13.	State/Local Penalty Required:	

- Was this a multi-media action? ○ Yes ● No
- Check all that make this action multi-media.
  ☐ Inspection ☐ Complaint ☐ Settlement ☐ SEP
- Geographic Initiative Area:
- MOA Priority/Sector:
- Was this Agency activity taken in response to Environmental Justice Concerns? ○ Yes ○ No
- Is this a Small Business? ○ Yes ○ No
- Was this a self-disclosure? ○ Yes ○ No

C. COST RECOVERY (Not Required for CAA)

D. SUPPLEMENTAL ENVIRONMENTAL PROJECT INFORMATION - (Complete Section if SEP included i

- Does SEP address any of the Region 5 Environmental Priorities? Toxics Reduction

15. Is Environmental Justice addressed by impact of SEP?

16. SEP Description: **8 Pump replacements with sealess technology , 3 Agitator replacements with sealess technology , and an enhanced LDAR Program**

17. Categories of SEP: **(1) equipment technology modifications , Other program specific SEP**

(Check all appropriate categories. If pollution prevention or pollution reduction is checked, pollutant, emission reductions and units should be reported below).

18. Cost of SEP (Cost Calculated by the PROJECT Model is preferred): **$630,000**

19. Quantitative environmental pollutants and/or chemicals and/or waste streams; amount of reductions/eliminations (e.g., emission/discharges):

SEP Pollutant	SEP Amount	SEP Units	SEP Media
TOTAL HAP POLLUTANT	46,880	Pounds	Air
			Air
			Air
			Air

E. INJUNCTIVE RELIEF/COMPLIANCE ACTION INFORMATION

20. What action did violator accomplish prior to receipt of settlement/order or will take to return to compliance or meet additional requirements (other than what has already been reported on the Inspection Conclusion Data Sheet (ICDS)). This may be due to settlement/order requirements or otherwise required by statute or regulation (e.g. actions related to an APO which did not specify compliance requirements). Where separate penalty and/or compliance orders are issued in connection w/same violation(s), report the following information for only one of those orders.

Actions with Direct Environmental Benefit and /or Direct Response /Corrective Action (Physical Actions).

(Pollutant reductions or environmental benefits must be quantified in Question 22)

21. Cost of Action:

22 Quantative environmental impact of actions described in #20 above:

*Pollutant/Land Use	*Amount	*Units/Acres (Express in annual amounts)	*Media
			Air
			Air
			Air
			Air

Facility Management and Information Practices (Non-Physical Actions):
(Actions will not result in pollutant reductions or environmental benefits If, Other is selected, please provide a description below)

22. Cost of Action:

Description of Injunctive Relief/Compliance Activity.

Preventive Actions to Reduce Likelihood of Future Releases :
(Only for Asbestos D/R settlements)

PLEASE ADD ADDITIONAL INFORMATION, INCLUDING SHORT (PUBLIC RELEASABLE) CASE SUMMARY. (The case summary should include the nature of the action and the problem to be addressed):

Pharmacia & Upjohn is primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The manufacturing of these pharmaceuticals requires the use of mulitple hazardous air pollutantss (HAPs), which makes the processing equipment subject to the requirements of the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for the Pharmaceutical Productions. Section 63.1255 of the regulations requires that monitoring comply with EPA Reference Method 21.

On November 1, 2004, EPA issued Findings of Violation to Pharmacia & Upjohn Company for alleging violations of the Pharmaceutical Productions NESHAP requirements. EPA found that Pharmacia & Upjohn failed to monitor its process components subject to LDAR requirements in accordance with EPA Reference Method 21.

As part of the settlement documented in the CAFO, an enhanced leak detection and repair program will be taken on by Pharmacia & Upjohn for a one-year period. Also, Pharmacia will replace 8

pumps and 3 agitators with sealess technology to decrease fugitive emissions. These projects are estimated to reduce HAPs emissions by at least 23.44 tons and will cost Pharmacia at least $630,000.